



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20-1242; Docket No. CDC-2020-0099]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Strengthening U.S. Response to Resistant Gonorrhea, which is to intended to enhance U.S. state and local public health surveillance and program infrastructure, build capacity to support rapid detection and public health response to antibiotic-resistant gonorrhea (an urgent public health threat), and advance the understanding of epidemiological factors contributing to antibiotic-resistant gonorrhea. CDC is requesting a three-year approval.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2020-0099 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

Strengthening U.S. Response to Resistant Gonorrhea (SURRG) (OMB Control No. 0920-1242, Exp. 9/30/2021) - Revision - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purposes of this Revision request for Strengthening U.S. Response to Resistant Gonorrhea (SURRG) are to: (1) improve national, state, and local capacity to rapidly detect, monitor, and respond to emerging antibiotic-resistant gonorrhea (and get actionable information to local health departments), (2) understand trends in and factors contributing to antibiotic-resistant gonorrhea, and (3) build a robust evidence base for

public health action. This information collection is important because: (1) effective treatment of gonorrhea is critical to gonorrhea control and prevention, (2) untreated or inadequately treated gonorrhea can cause serious reproductive health complications, such as infertility, (3) *Neisseria gonorrhoeae* (the bacterium that causes gonorrhea) has consistently demonstrated the ability to develop antibiotic resistance and may be developing resistance to the last remaining treatment option recommended by the Centers for Disease Control and Prevention (CDC), and (4) antibiotic-resistant gonorrhea is extremely difficult to detect without enhanced surveillance and public health activities, such as SURRG, because healthcare providers rarely perform or have access to culture and resistance testing for individual patients.

Jurisdictions participating in SURRG applied as part of a competitive process and will participate voluntarily. As an overview of SURRG, healthcare providers at participating clinics collect specimens for *N. gonorrhoeae* culture testing. Specimens that demonstrate *N. gonorrhoeae* (called "isolates") rapidly undergo antibiotic resistance testing at the local public health laboratory. Detection of resistance is rapidly communicated by laboratory staff to the healthcare provider and health department. The patient (from whom the resistant specimen was collected) is interviewed by local health department staff about

risk factors and recent contacts, and will be re-tested to ensure that they were cured. Recent contacts are interviewed by the health department (contact tracing) and tested for gonorrhea. The participating health departments collect and transmit to CDC demographic and clinical data about persons tested for and diagnosed with gonorrhea in the participating clinics, results of local antibiotic resistance testing, and information about field investigations. None of the data transmitted to CDC contains any personally identifiable information. These data are used by CDC to monitor and better understand resistance and identify effective approaches to prevent resistance spread. Data are transmitted to CDC through a secure encrypted file transfer application and stored in a secure CDC server with strictly controlled and restricted access rights.

In processes that take approximately 16 hours every two months (plus an annual cumulative datafile), local SURRG data managers abstract STD clinic data for patients tested for gonorrhea and field investigation data, receive gonorrhea data from non-STD clinic healthcare sites and resistance testing results from local public health laboratories, and clean and transmit data to CDC.

Other data managers at each participating non-STD clinic health center abstract, clean, and transmit data (approximately

three hours every two months). Microbiologists at public health laboratories from each funded jurisdiction conduct resistance testing on ~700 *N. gonorrhoeae* isolates each year (600 clinical isolates and 100 control strains; each test ~10 minutes). Laboratory data managers take about one hour every two months to abstract, clean, and transmit data.

Health department staff will interview: any person diagnosed with antibiotic-resistant gonorrhea or have a case of gonorrhea of public health significance index case, and their sexual contacts. On average, each jurisdiction will identify four drug-resistant isolates each month; these isolates will spur field investigations and six additional interviews monthly. We estimate a total of 120 interviews annually at each site, for a total across the eight sites of 960 interviews each year. Each interview will take ~20 minutes.

The total estimated annual burden hours are 2,665. This burden represents a decrease from the burden of the initial submission. The number of jurisdictions decreased from nine to eight. So the number of local data managers decreased from nine to eight (and the burden hours decreased from 1008 to 896), the number of public health microbiologists decreased from nine to eight (burden hours decreased from 1050 to 933), the number of lab data managers decreased from nine to eight (burden hours decreased from 54 to 48), and the number of gonorrhea and

contacts decreased from 1080 to 960 (burden hours decreased from 540 to 480). The number of clinic sites will increase from 18 to 26. Respondents receive federal funds to participate in this project. There are no additional costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (Hours)	Total Burden Hours
Local SURRG data manager	STD Clinic Facility Data Elements	8	7	16	896
Data manager at non-STD clinic health centers	Non-STD Clinic Facility Data Elements	26	6	3	468
Public Health Laboratory Microbiologist	Laboratory Data Elements	8	700	10/60	933
Public Health Laboratory Data Manager	Laboratory Testing Data Elements	8	6	1	48
Gonorrhea Patients, Social and Sexual Contacts	Investigation Data Elements	960	1	0.33	320
Total					2,665

Jeffery M. Zirger,

Lead,

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Office of Scientific Integrity,
Office of Science,
Centers for Disease Control and Prevention.*

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